UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,290	02/25/2002	Masaaki Kosaka	350292001300	1521

25227 7590 02/04/2005

MORRISON & FOERSTER LLP
1650 TYSONS BOULEVARD
SUITE 300
MCLEAN, VA 22102

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,290	KOSAKA ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☑ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/25/02, 12/17/02, 4/4/03, 4/13/03, 7/1/04 & 8/17/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of Applicants' response filed 11/8/2004 to restriction/election of Group I drawn to claims 1-8 with partial traverse is acknowledged. Applicants have requested that the Office join groups II and V because claims 9-17 and 21-28 are drawn to the same or corresponding special technical feature , namely the enhancement of the expression of HM1.24 antigen using the amino acid sequence of SEQ ID NO: 2. This is not found to be persuasive because the enhancer composition in claims 1 and 9 are different. The enhancer used in claim 1 is interferon α or γ. However, claim 9 uses IRF-2. Further, contrary to Applicants' assertion that the Office did not provide applicable prior art to indicate the lack of the same or corresponding technical feature, the Office did provide Arora et al. (1998), which describes a composition comprising interferon α used to stimulate expression in myeloma cell lines. Thus, the restriction requirement is deemed proper and made FINAL. Therefore, claims 1-8 will be considered as drawn to the elected group.

Information Disclosure Statement

2. The PTO-1449s submitted on 4/25/2002, 12/ 17/2002, 4/4/2003, 11/13/2003, 7/1/2004 and 8/17/2004 are acknowledged.

Drawings

3. The drawing submitted on 2/25/2002 is acknowledged.

Priority

4. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Arora et al. (1998).

Arora et al. (1998) describe compositions comprising interferon-α as an active ingredient. The reference teaches that interferon-α has been used as therapy for the treatment of a variety of viral diseases and malignancies including multiple myeloma (see abstract). The intended use in the instant invention has no patentable weight and thus the limitations for claim 1 is taught by Arora et al. (1998)). Therefore, claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Arora et al. (1998) reference provided in the PTO-892 of 10/06/04.

5b. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Bungard et al. (1998).

Bungard et al. (1998) teach that antibody-dependent cell-mediated cytotoxicity (ADCC) of mAb 17-1A and the mAb BR55-2 against colorectal carcinoma is enhanced

by the treatment of cytokines including interferon-α, interferon-γ and IL-2. The intended use in the instant invention has no patentable weight and thus the limitations for claim 1 is also taught by Bungard et al. (1998). Therefore, claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bungard et al. (1998)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6a. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozaki et al (1997) in view of Bungard et al. (1998) and Koishihara et al. (U. S. Patent. No: 6, 503, 510).

Ozaki et al. (1997) teach that anti-HM1.24 Moab (monoclonal antibody) can be used for immunotherapy of multiple myeloma (see abstract). The reference teaches that the anti-HM1.24 MoAb in a dose dependent manner inhibited the tumor growth (p. 3182, 1st paragraph). Ozaki et al. show that complement-dependent cytotoxicity and antibody-dependent cell-mediated cytotoxicity (ADCC) were mediated by very low concentration of anti-HM1.24 antibody (p. 3182, 4th paragraph). It is further taught that immunotherapy using anti-HM1.24 MoAb can be applicable to myeloma patients especially when significant tumor reduction has been achieved by conventional and/or high-dose chemotherapy with stem cell support (p. 3185, 2nd paragraph). In addition, they indicate that administration of cytokines, such as IL-2, IL-10, IL-12, macrophage colony-stimulating factor (M-CSF), has been shown to increase the levels of ADCC by the stimulation of effector cells, suggesting the combinations of these cytokines along with the antibody to further potentiate the effect of the antibody support (p. 3185, 2nd paragraph). Thus meeting the limitations of dependent claims 2 (part of), 3, 4, 5 and 7. However, it does teach the use of an antibody in combination with cytokines like interferon-α or interferon-γ.

Bungard et al. (1998) teach that ADCC of mAb 17-1A and the mAb BR55-2 against colorectal carcinoma is enhanced by the treatment of cytokines including interferon-α, interferon-γ and IL-2.

Koishihara et al. (U. S. Patent. No: 6, 503, 510) describes anti-HM1.24 antibody that has cytotoxic activity that binds to SEQ ID NO: 2 of the instant invention (see column 3 lines 1-17). Thus meeting the limitations of dependent claims 2 (part of) and 7.

It also describes monoclonal antibodies, chimeric antibodies and humanized antibodies, thus meeting the limitations of the dependent claims 4-8 (column 8, lines 4-30). In addition, it also teaches a therapeutic agent containing as an active ingredient (anti-HM1.24 antibody) a chimeric antibody or humanized antibody that specifically binds to a protein having the amino acid sequence as set forth in SEQ ID NO: 5 (see Appendix A), thus meeting the limitations of the dependent claims 4-8 (columns 2-3).

Therefore, it would have been *prima facie* obvious at the time of the invention to generate therapeutic agents for myeloma comprising anti-HM1.24 antibodies disclosed in Ozaki et al., because Ozaki reference demonstrates that anti-HM1.24 antibodies inhibit tumor growth, and Bungard et al. teach that antibody-dependent cell-mediated cytotoxicity of specific antibodies against tumors are enhanced by the treatment with cytokines including interferon-α, interferon-γ and IL-2. In addition, Koishihara et al. describe the limitations present in claims 2 and 4-8, which recite the binding of HM1.24 antibody to SEQ ID NO: 2 and the variation of antibodies used respectively. Thus, it would have been obvious to one of skill in the art to generate therapeutic agents for myeloma comprising anti-HM1.24 antibodies and interferon α or γ disclosed by Bungard et al., to maximize the ADCC. One of ordinary skill in the art would have been motivated to generate therapeutic agents for myeloma containing HM1.24 antibodies and interferon α or γ compositions described both by Ozaki et al. and/or Koishihara et al., and because Bungard et al. have showed that ADCC of specific antibodies against tumor is enhanced by the treatment with cytokines including interferon-α, interferon-γ

and IL-2. Therefore, the instant invention is obvious over over Ozaki et al (1997) in view of Bungard et al. (1998) and Koishihara et al. (U. S. Patent. No: 6, 503, 510).

7. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSS 1/05

JANET ANDRES
PRIMARY EXAMINER

```
  Best Local Similarity   100.0%;  Pred. No. 2.4e-84;
  Matches  172;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MASTSYDYCRVPMEDGDKRCKLLLGIGILVLLIIVILGVPLIIFTIKANSEACRDGLRAV 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MASTSYDYCRVPMEDGDKRCKLLLGIGILVLLIIVILGVPLIIFTIKANSEACRDGLRAV 60

Qy         61 MECRNVTHLLQQELTEAQKGFQDVEAQAATCNHTVMALMASLDAEKAQGQKKVEELEGEI 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 MECRNVTHLLQQELTEAQKGFQDVEAQAATCNHTVMALMASLDAEKAQGQKKVEELEGEI 120

Qy        121 TTLNHKLQDASAEVERLRRENQVLSVRIADKKYYPSSQDSSSAAAPQLLIVL 172
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TTLNHKLQDASAEVERLRRENQVLSVRIADKKYYPSSQDSSSAAAPQLLIVL 172


RESULT 2
US-09-818-648-1
; Sequence 1, Application US/09818648
; Patent No. 6489126
;   GENERAL INFORMATION:
;        APPLICANT: HIRANO, TOSHIO
;                   KAISHO, TSUNEYASU
;        TITLE OF INVENTION: MEMBRANE PROTEIN POLYPEPTIDE HAVING
;                            PRE-B CELL GROWTH-SUPPORTING ABILITY AND A GENE THEREOF
;        NUMBER OF SEQUENCES: 2
;        CORRESPONDENCE ADDRESS:
;             ADDRESSEE: OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT,
;                        P.C.
;             STREET: 1755 S. JEFFERSON DAVIS HIGHWAY, SUITE 400
;             CITY: ARLINGTON
;             STATE: VA
;             COUNTRY: USA
;             ZIP: 22202
;        COMPUTER READABLE FORM:
;             MEDIUM TYPE: Floppy disk
;             COMPUTER: IBM PC compatible
;             OPERATING SYSTEM: PC-DOS/MS-DOS
;             SOFTWARE: PatentIn Release #1.0, Version #1.30
;        CURRENT APPLICATION DATA:
;             APPLICATION NUMBER: US/09/818,648
;             FILING DATE: 28-Mar-2001
;             CLASSIFICATION: <Unknown>
;        PRIOR APPLICATION DATA:
;             APPLICATION NUMBER: US/08/624,650
;             FILING DATE: 22-MAY-1996
;             APPLICATION NUMBER: PCT/JP94/01732
;             FILING DATE: 14-OCT-1994
;             APPLICATION NUMBER: JP 5-281622
;             FILING DATE: 15-OCT-1993
;        ATTORNEY/AGENT INFORMATION:
;             NAME: OBLON, NORMAN F.
;             REGISTRATION NUMBER: 24,618
;             REFERENCE/DOCKET NUMBER: 7625-001-0 PCT
;        TELECOMMUNICATION INFORMATION:
;             TELEPHONE: 703-413-3000
;             TELEFAX: 703-413-2220
;   INFORMATION FOR SEQ ID NO: 1:
;        SEQUENCE CHARACTERISTICS:
;             LENGTH: 180 amino acids
;             TYPE: amino acid
;             STRANDEDNESS: single
;             TOPOLOGY: linear
;        MOLECULE TYPE: peptide
;        SEQUENCE DESCRIPTION: SEQ ID NO: 1:
US-09-818-648-1

  Query Match             100.0%;  Score 854;  DB 4;  Length 180;
  Best Local Similarity   100.0%;  Pred. No. 2.4e-84;
  Matches  172;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MASTSYDYCRVPMEDGDKRCKLLLGIGILVLLIIVILGVPLIIFTIKANSEACRDGLRAV 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db          1 MASTSYDYCRVPMEDGDKRCKLLLGIGILVLLIIVILGVPLIIFTIKANSEACRDGLRAV 60

Qy         61 MECRNVTHLLQQELTEAQKGFQDVEAQAATCNHTVMALMASLDAEKAQGQKKVEELEGEI 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db         61 MECRNVTHLLQQELTEAQKGFQDVEAQAATCNHTVMALMASLDAEKAQGQKKVEELEGEI 120

Qy        121 TTLNHKLQDASAEVERLRRENQVLSVRIADKKYYPSSQDSSSAAAPQLLIVL 172
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TTLNHKLQDASAEVERLRRENQVLSVRIADKKYYPSSQDSSSAAAPQLLIVL 172


RESULT 3
US-09-355-925-5
; Sequence 5, Application US/09355925
; Patent No. 6503510
; GENERAL INFORMATION:
;  APPLICANT:  KOISHIHARA, YASUO
;  APPLICANT:  YOSHIMURA, YASUSHI
;  TITLE OF INVENTION:  THERAPEUTIC AGENT FOR LYMPHATIC TUMORS
;  FILE REFERENCE:  053466/0255
;  CURRENT APPLICATION NUMBER: US/09/355,925
;  CURRENT FILING DATE:  1999-08-11
;  PRIOR APPLICATION NUMBER:  PCT/JP98/00568
;  PRIOR FILING DATE:  1998-02-12
;  PRIOR APPLICATION NUMBER:  JP 9-41410
;  PRIOR FILING DATE:  1997-02-12
;  NUMBER OF SEQ ID NOS:  8
;  SOFTWARE:  PatentIn Ver. 2.1
; SEQ ID NO 5
;   LENGTH: 180
;   TYPE: PRT
;   ORGANISM: Homo sapiens
;   FEATURE:
;   OTHER INFORMATION: Amino acid sequence of HM1.24 antigen
US-09-355-925-5

  Query Match             100.0%;  Score 854;  DB 4;  Length 180;
  Best Local Similarity   100.0%;  Pred. No. 2.4e-84;
  Matches  172;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MASTSYDYCRVPMEDGDKRCKLLLGIGILVLLIIVILGVPLIIFTIKANSEACRDGLRAV 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db          1 MASTSYDYCRVPMEDGDKRCKLLLGIGILVLLIIVILGVPLIIFTIKANSEACRDGLRAV 60

Qy         61 MECRNVTHLLQQELTEAQKGFQDVEAQAATCNHTVMALMASLDAEKAQGQKKVEELEGEI 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db         61 MECRNVTHLLQQELTEAQKGFQDVEAQAATCNHTVMALMASLDAEKAQGQKKVEELEGEI 120

Qy        121 TTLNHKLQDASAEVERLRRENQVLSVRIADKKYYPSSQDSSSAAAPQLLIVL 172
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TTLNHKLQDASAEVERLRRENQVLSVRIADKKYYPSSQDSSSAAAPQLLIVL 172


RESULT 4
US-09-787-375-2
; Sequence 2, Application US/09787375
; Patent No. 6602663
; GENERAL INFORMATION:
;  APPLICANT: KAWAI, SHIGETO
;  APPLICANT:  KOISHIBARA, YASUO
;  TITLE OF INVENTION: METHOD FOR DETECTION OR MEASUREMENT OF PLASMACYTOMA CELLS
;  FILE REFERENCE: 053466/0301
;  CURRENT APPLICATION NUMBER: US/09/787,375
;  CURRENT FILING DATE:  2001-03-16
;  PRIOR APPLICATION NUMBER: PCT/JP99/04502
;  PRIOR FILING DATE: 1999-08-20
;  PRIOR APPLICATION NUMBER: JP 10-264593
;  PRIOR FILING DATE: 1998-02-18
;  NUMBER OF SEQ ID NOS: 5
;  SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 2
;   LENGTH: 180
;   TYPE: PRT
```